Reviewer's report

Title: Examining assumptions regarding valid electronic monitoring of medication therapy: development of a validation framework and its application on a European sample of kidney transplant patients

Version: 2 Date: 24 November 2007

Reviewer: Jesse Berlin

Reviewer's report:

General

Comments from Jesse Berlin
Re: 'Examining assumptions regarding valid electronic monitoring of medication therapy: development of a validation framework and its application on a European sample of kidney transplant patients'
Kris Denhaerynck, Petra Schafer-Keller, James Young, Jurg Steiger, Andreas Bock and Sabina De Geest
BMC Medical Research Methodology
Research article

Resolving the differences in perception between Reviewer 3 and the authors:

In the end, I'm not sure there is a right or wrong answer to the debate between the authors and the referee regarding the participant self-reports of discrepancies between EM and actual adherence. Dr. Urquhart focuses on the interviews, and potential for bias being introduced in the interview process, whereas the authors seem to be focusing more on the forms that were completed by the patients themselves. In fact, I saw very little (if any) mention of the results of the interviews. Perhaps the original paper was not clear on the source of the data regarding the discrepancies. Still, Dr. Urquhart makes a very valid point, that self-reports of good adherence might not be very valid. This point is now clearly acknowledged by the authors, who make what I think is an equally valid point, that it’s also hard to ignore the self-reported explanations for discrepancies. As they note in their reply to Dr. Urquhart, “Even if less reliable than other sources, this kind of patient report may result in a more accurate measurement than simply not correcting phantom missing data.”

Dr. Urquhart provides an explanation for increasing adherence over time, whereas the authors noted a very slight increase in non-adherence over time. I wasn’t quite sure where that discussion was going, but agree completely with Dr. Urquhart that the changes over time were so small that they could be considered of trivial clinical importance. The authors make this point, but should probably strengthen that part of their discussion to better reflect this acknowledgement. Their statement on page 14, that “A subsequent increase of non-adherence
probably reflects the waning of the adherence-enhancing effect of introducing EM to patients’ daily lives”, I believe is a bit of an overinterpretation of those very small changes.

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Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

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Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

1. page 11, first paragraph: “Thirty-four (12%) patients were excluded from the analyses because they failed to adhere to the EM guidelines.” What does this mean? What was the nature of the failure? What distinguishes these violations from the sort of discrepancies that were captured on the forms for patients who remained in the study?

2. page 12, first paragraph: Similar point for the 23 patients who had “defined periods of non-adherence to the guidelines of correct EM use.” What constitutes one of these periods?

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Discretionary Revisions (which the author can choose to ignore)

What next?: Accept after minor essential revisions

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I have no competing interests.